

## REMARKS

In the Office Action, claims 1, 2, 9-11, and 13-16 are rejected under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 4,713,974 issued to Stone (hereinafter "Stone"). Claims 3-6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stone in view of United States Patent No. 5,632,895 issued to Tsukagoshi et al. (hereinafter "Tsukagoshi") (together "Cited References"). Applicants respectfully traverse the rejections. The Examiner further indicated that claims 7 and 8 would be allowable if rewritten to include all of the limitations of their respective base claims and any intervening claims. At the outset, Applicants express their appreciation to Examiner Cross for the courtesies extended during the telephonic interview of December 16, 2004.

Applicants respectfully traverse the rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by Stone. (An anticipation rejection is proper, "only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." See MPEP § 2131.) Applicants submit that Stone fails to anticipate claim 1 because it fails to disclose, expressly or inherently, among other things, "an apparatus comprising . . . **a sealing boot**," as recited in claim 1.

In the telephonic interview of December 16, 2004, the Examiner indicated that the device disclosed in Stone could assume a configuration where the vial stabilizer 320 of Stone came into contact with the needle housing 280 of Stone. The Examiner reasoned that a seal could then form between the vial

stabilizer 320 and needle housing 280.<sup>1</sup> Accordingly, the Examiner concluded that the vial stabilizer 320 of Stone is equivalent to the sealing boot of claim 1.

Applicants submit that, (1) Stone does not expressly disclose any kind of seal or “sealing boot” as recited in claim 1; (2) the disclosure of Stone suggests that the Examiner’s interpretation, as set forth in the telephone interview, is incorrect; and (2) even if the Examiner’s reasoning is correct, Stone does not expressly, or inherently, teach a sealing boot.

First, the disclosure of Stone does not expressly teach any kind of sealing boot. The Examiner cites Stone’s vial stabilizer 320 as equivalent to the claimed sealing boot, but fails to point to any express teaching in Stone that the vial stabilizer 320 forms any kind of seal. Applicants submit that there is no express teaching in Stone that the vial stabilizer 320 forms any kind of seal, and therefore the vial stabilizer 320 is not a sealing boot, and Stone cannot expressly anticipate claim 1.

The Examiner seems to reason that, despite the lack of any express teaching, the apparatus of Stone is capable of forming a seal if the vial stabilizer 320 is brought into contact with its needle housing 280. Applicants submit that this reasoning is not a correct interpretation of Stone. In fact, Stone suggests that its vial stabilizer 320 never actually contacts the needle housing 280, let alone forms any kind of seal. Stone teaches that, “[w]hen the vial is fully elevated lower flag 222 interrupts the light path of optical sensor 224 alerting the processor to stop the lifting action of the motor 240.” (See Stone at Column 7, lines 38-46.) Fig. 4 of Stone shows the lower flag 222 interacting with the optical sensor 224, indicating that the vial is in its “fully

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<sup>1</sup> Applicants do not concede that any seal would be formed if the vial stabilizer 320 of Stone were to be brought in contact with the needle housing 280.

elevated” position. (See Stone at Fig. 4.) Even in this “fully elevated” position, there is still a clearly noticeable distance between the vial stabilizer 320 and needle housing 280 of Stone. The flags and optical sensors of Stone are designed to stop upward motion when the needle engages the bottom of the vial, not when, and apparently before, the vial stabilizer 320 contacts the needle assembly 280. (See Stone at Column 6, lines. 46-53.)

Even if the Examiner’s interpretation of Stone were correct, it is not sufficient to establish that Stone inherently teaches a “sealing boot” as recited in claim 1. Applicants refer the Examiner to MPEP § 2112, Section IV. Entitled, “Examiner Must Provide Rationale Or Evidence Tending To Show Inherency:”

**The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.** *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. **Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.**’ *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.).

(emphasis added). The Examiner merely states that in a given set of circumstances, *i.e.* the vial stabilizer 320 is brought in contact with the needle housing 280, a seal may result. Applicants submit that this does not establish that the result, a seal, is inherent in the Stone reference. *See* MPEP § 2112. Accordingly, Applicants submit that Stone fails to expressly or inherently teach a “sealing boot” as recited in claim 1. Therefore, claim 1 and claims 2-11 that depend therefrom are not anticipated by Stone.

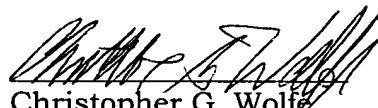
Applicants further submit that claims 13 and 15, like claim 1, recite a “sealing boot.” Therefore, Stone does not anticipate claims 13 and 15 as well as claim 14, which is dependent from claim 13 for the same reasons outlined above with respect to claim 1.

Applicants are not otherwise conceding the correctness of the Office’s rejection with respect to any of the dependent claims discussed above and hereby reserve the right to make additional arguments as may be necessary because the dependent claims include additional features that further distinguish the claims from the Cited References, taken alone or in combination. A detailed discussion of these differences is believed to be unnecessary at this time in view of the basic differences in the independent claims pointed out above.

### CONCLUSION

Applicants have made a diligent effort to fully respond to all the concerns and comments of the Examiner. Therefore, Applicants respectfully request that a timely Notice of Allowance be issued in the subject application. If the Examiner has any concerns regarding Applicants' present response, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below so that those concerns may be expeditiously addressed.

Respectfully submitted,

  
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